

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO**

IN RE PRESCRIPTION
OPIATE LITIGATION

This document relates to:
Case No. 1:19-op-45346-DAP

DURHAM COUNTY,

Plaintiff,

vs.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**KROGER DEFENDANTS' ANSWER TO PLAINTIFF'S
SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO
"SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING
DEFENDANTS AND JURY DEMAND"**

Defendants, The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II, Harris Teeter, LLC f/k/a Food World, Inc. f/k/a Harris Teeter, Inc. f/k/a Harris Teeter Super Markets, Inc. f/k/a Racc, Inc.¹ (collectively "Kroger"), pursuant to the Stipulated Order Regarding Answering the May 19, 2021 Amended Complaints in the Five New Pharmacy Bellwether Cases (MDL ECF No. 3853, the "Stipulated Order"), answer Plaintiff's "Supplemental and Amended Allegations to be Added to 'Short Form for Supplementing Complaint and Amending Defendants and Jury Demand'" (ECF No. 20, the "Amended Complaint") as follows:

¹ The "Harris Teeter" Defendant is incorrectly named. The actual entity is Harris Teeter LLC f/k/a Harris Teeter, Inc., f/k/a RDK Investment Company and Harris Teeter Supermarkets, Inc. Kroger refused to sign a waiver of service for Harris Teeter as named and instead signed a waiver of service for the correct Harris Teeter name. Plaintiff has not responded or tried to correct the error.

Statements Pursuant to Stipulated Order

A. Pursuant to the Stipulated Order (§ 4), Kroger has no obligation to answer any prior complaints and pleadings incorporated by reference into the Amended Complaint. By not answering such prior complaints and pleadings, Kroger does not admit any of the allegations in those prior complaints or pleadings and reserves all defenses to the claims and allegations of the prior complaints or pleadings. The fact that Kroger has not answered any prior complaints and pleadings in responding to the allegations of the Amended Complaint, based on the Stipulated Order, shall not and cannot be construed as an admission of any allegation in those prior complaints or pleadings and shall not be a basis for a default judgment with respect to any claims asserted in those prior complaints or pleadings. On this basis, Kroger does not answer 3, 723-724 and 727 of the Amended Complaint. For clarity, Kroger denies any incorporated allegations to the extent they are directed at Kroger and denies them specifically to the extent they claim Kroger acted improperly or failed to comply with the law. To the contrary, Kroger, at all times, acted properly and in accordance with its legal obligations. Kroger denies any and all liability to the Plaintiff in this matter.

B. Kroger answers only for itself. Pursuant to the Stipulated Order (§ 5), Kroger has no obligation to answer any allegation or paragraph directed solely to other defendants and may so state in its Answer. On this basis, Kroger does not answer paragraphs 33-80, 191-453, 480-483, 486-502, 507, 511-512, 516, 524-525, 534-538, 544-571, 573, 580-590, and 598-644 of the Amended Complaint. For clarity, Kroger denies any averments directed at Kroger, including in these paragraphs.

C. Pursuant to the Stipulated Order (§§ 6, 9), Kroger may identify the paragraphs that it denies in their entirety by paragraph number. Additionally, the Amended Complaint contains purported references to several documents and third-party publications and

statements that have often been excerpted, paraphrased, characterized, and otherwise taken out of context. These third-party publications and statements should be considered, if at all, in context and in unmodified form, and Kroger hereby respectfully refers the Court to the respective third-party publications and statements for their complete contents. On this basis, Kroger denies paragraphs 1-2, 4-32, 88-103, 105-151, 153-190, 478-479, 484-485, 503-506, 508-510, 513-515, 518-523, 526-533, 539-543, 574-579, 592-597, 646-722, 725-726, and 728-764 of the Amended Complaint: as factually incorrect; as calling for legal conclusions; as purporting to state facts as to which Kroger lacks sufficient knowledge to respond; as based on the Plaintiff's vague, ambiguous, and improper characterizations; and/or to the extent Plaintiff's purport to quote from sources other than the Amended Complaint, including undisclosed or unidentified sources. Kroger specifically denies any and all allegations that it distributed or dispensed opioid medications in violation of the Controlled Substances Act, its associated regulations, or any other state or federal law or regulation. Kroger also specifically denies that its distribution of opioid medications to Kroger pharmacies or dispensing of those medications from those Kroger pharmacies caused or contributed to any public nuisance, and denies allegations directed against Kroger in those paragraphs.

Preliminary Statement

A. Kroger does not contest that there are certain harms associated with improper opioid use, including opioid addiction; however, Kroger's overriding contention in this Answer is simply that it is not responsible or liable for the allegations made in the Amended Complaint or the choices certain individuals may have made to use opioid medications improperly and any resulting harms to those individuals or third parties.

B. All subparts, footnotes, headings, or graphical addenda in Paragraphs in the Amended Complaint are treated as part of the Paragraph that is being responded to and are not

separately dealt with. To the extent these materials need to be specifically addressed, Kroger denies them.

C. Kroger denies each allegation contained in the Amended Complaint, except as specifically admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos, or speculation contained in any averment or in the Amended Complaint, as a whole.

D. The Amended Complaint contains and references documents, websites, books, guides, pamphlets, articles, third-party publications, and statements that are excerpted, paraphrased and characterized. Such items constitute the best evidence and speak for themselves, and references to them should be considered, if at all, in context and in unmodified form. Kroger objects to the references to such items to the extent the proper foundation has not been established and require review of information outside the pertinent pleadings, and Kroger denies any characterizations thereof. To the extent such items are considered, Kroger respectfully refers the Court to the respective materials for their complete contents.

E. The Amended Complaint, on occasions, uses vague and ambiguous language, like “substantial,” “multiple sources,” and an undefined “etc.” On such occasions, Kroger has no recourse but to deny those allegations, based on imprecise terminology.

F. Kroger admits that certain provisions of state and federal law impose a duty on it to report suspicious orders and other responsibilities, and states that Kroger fulfilled that duty and those responsibilities, and denies any allegations directed at Kroger, based on duties and obligations imputed by Plaintiff on Kroger.

G. With respect to paragraphs in the Amended Complaint alleging the DEA’s reminders of obligations, Distributors’ Initiatives, conferences, guidance, letters, instructions,

meetings, and presentations, Kroger asserts that such DEA actions speak for themselves, and Kroger denies any characterizations thereof, denies any allegations directed at Kroger, but Kroger is without knowledge or information sufficient to form a belief as to the truth of the allegations in those Paragraphs of the Amended Complaint and, on that basis, denies those allegations.

H. Kroger reserves the right to seek to amend and supplement its Answer as may be appropriate or necessary.

Answers to Remaining Allegations

The paragraphs below Answer the correspondingly enumerated paragraphs of the Amended Complaint.

81. Kroger admits the allegations in Paragraph 81 of the Amended Complaint.

82. Kroger admits the allegations in Paragraph 82 of the Amended Complaint.

83. Kroger admits that Kroger Limited Partnership is an Ohio limited partnership and denies the remaining allegations in Paragraph 83 of the Amended Complaint.

84. Kroger objects to Paragraph 84 of the Complaint as impermissibly vague and ambiguous (“at all times relevant”) and hence denies those allegations. Kroger admits that Defendant Harris Teeter, LLC f/k/a Food World, Inc. f/k/s Harris Teeter, Inc. f/k/a Harris-Teeter Super Markets, Inc. f/k/a Racc, Inc. (“Harris Teeter”) is registered to do business in North Carolina as a North Carolina limited liability company with its principal place of business in North Carolina. Kroger states that, in or around 2014, it acquired Harris Teeter, that the article cited by the Plaintiff speaks for itself, and denies any mischaracterizations thereto.

85. Kroger asserts that Paragraph 85 of the Amended Complaint refers to a nomenclature utilized by the Plaintiff to which no response is required, and denies any allegations directed at Kroger.

86. Kroger admits that it operates approximately 2,200 pharmacies in certain areas of the United States and admits the remaining allegations in Paragraph 86 of the Amended Complaint.

87. Kroger objects to Paragraph 87 of the Amended Complaint as impermissibly vague and ambiguous (“all relevant times” and “certain drugs”), and hence denies those allegations, and further admits only that it self-distributed hydrocodone to its pharmacies until 2014, and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 87 and, on that basis, denies those allegations.

104. Kroger objects to Paragraph 104 of the Complaint as impermissibly vague and ambiguous (“substantial business”) and hence denies those allegations. Kroger admits only that it operates over 2,200 pharmacies in certain areas of the United States, including North Carolina, that it self-distributes certain prescription medications to its pharmacies, that its pharmacies dispense prescription medications, denies the remaining allegations directed at Kroger, and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 104 of the Amended Complaint and, on that basis, denies those allegations.

152. Kroger admits that NACDS is a trade association that, *inter alia*, represents pharmacies, that the NACDS Board promulgates strategy for the association, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 152 of the Amended Complaint and, on that basis, denies those allegations.

454. Kroger admits only that it had certain pertinent information relating to filling of prescription procedures at its pharmacies, that it followed federal and state laws relating

to its dispensing and internal distribution actions, and denies the remaining allegations in Paragraph 454 of the Amended Complaint.

455. Kroger denies the allegation in Paragraph 455 of the Amended Complaint.

456. Kroger denies that it distributed any Oxycodone, asserts that the ARCOS data speaks for itself, and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 456 of the Amended Complaint and, on that basis, denies those allegations.

457. Kroger denies the allegation in Paragraph 457 of the Amended Complaint.

458. Kroger denies the allegation in Paragraph 458 of the Amended Complaint.

459. Kroger denies the allegation in Paragraph 459 of the Amended Complaint.

460. Kroger objects to Paragraph 460 of the Amended Complaint as impermissibly vague and ambiguous (“purchased” is undefined, and there are undefined pharmacy locations except for one named entity), and hence denies those allegations, and further asserts that the ARCOS data speaks for itself.

461. Kroger objects to Paragraph 461 of the Amended Complaint as impermissibly vague and ambiguous (“Three Kroger stores”), and hence denies those allegations, and further asserts that the ARCOS data speaks for itself.

462. Kroger objects to the undefined timeframe, quotations, and terms such as “appears” and “aiming” as impermissibly vague and ambiguous, and hence denies those allegations. Answering further, Kroger’s process for reviewing orders has evolved over time. Kroger admits that its Pharmacy Managers review certain opioid orders, admits that Kroger has computer and other systems in place that track inventory, admits that its Pharmacy Coordinators could launch inquiries and conduct internal investigations about a single pharmacy’s opioid

medication orders and activity, and denies the remaining allegations in paragraph 462 of the Amended Complaint.

463. Kroger objects to the undefined quotations in Paragraph 463 of the Amended Complaint, as impermissibly vague and ambiguous, and hence denies those allegations, and further states that any documents referenced in Paragraph 463 collectively and in their entirety speak for themselves, and Kroger denies any characterization thereof.

464. Kroger objects to Paragraph 464 of the Amended Complaint as it is impermissibly vague and ambiguous, and does not define the document or who utilized it, and, on that basis, denies those allegations. Answering further, Kroger asserts that its SOM training materials in their entirety speak for themselves, and Kroger denies any mischaracterization thereof.

465. Kroger denies the allegation in Paragraph 465 of the Amended Complaint.

466. Kroger denies the allegation in Paragraph 466 of the Amended Complaint.

467. Kroger denies the allegation in Paragraph 467 of the Amended Complaint.

468. Kroger denies the allegation in Paragraph 468 of the Amended Complaint.

469. Kroger denies the allegation in Paragraph 469 of the Amended Complaint.

470. The DEA's investigation of any Kroger entity speaks for itself, and Kroger denies any characterization thereof, and denies the remaining allegations in Paragraph 470 of the Amended Complaint.

471. The DEA's settlement with any Kroger entity speaks for itself, and Kroger denies any characterization thereof; Kroger also asserts that any settlements are confidential, and denies the remaining allegations in Paragraph 471 of the Amended Complaint.

472. The DEA's press release concerning settlement with any Kroger entity speaks for itself, and Kroger denies any characterization thereof, and asserts that it followed federal

and state laws relating to its dispensing and internal distribution actions, and denies the remaining allegations in Paragraph 472 of the Amended Complaint.

473. Kroger denies the allegation in Paragraph 473 of the Amended Complaint.

474. Kroger denies the allegation in Paragraph 474 of the Amended Complaint.

475. Kroger objects to the undefined timeframe as impermissibly vague and ambiguous, and hence denies those allegations. Answering further, Kroger asserts that these processes have evolved over time, Kroger admits that its pharmacies obtain opioids and other prescription medicines from self-distribution, and from Cardinal Health, and receives communications from Cardinal Health, and denies the remaining allegations in Paragraph 475 of the Amended Complaint.

476. Kroger admits that it utilizes a program called NARxCHECK where available, the program has certain specifications, informational aspects, and benefits, that speak for themselves, and Kroger denies any characterization thereof, and denies the remaining allegations in Paragraph 476 of the Amended Complaint.

477. Kroger denies the allegation in Paragraph 477 of the Amended Complaint.

517. Kroger denies the allegation in Paragraph 517 of the Amended Complaint.

572. Kroger denies the allegations in Paragraph 572 of the Amended Complaint directed at Kroger and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 572 of the Amended Complaint and, on that basis, denies those allegations.

591. Paragraph 591 of the Amended Complaint refers to a Cardinal document that speaks for itself, and Kroger denies any characterization thereof, but Kroger is without

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 612 of the Amended Complaint and, on that basis, denies those allegations.

645. Paragraph 645 of the Amended Complaint references two DEA settlements that speak for themselves, and Kroger denies any characterizations thereof, and Kroger asserts that the settlements are confidential. Answering further, Kroger asserts that the settlement referenced in Paragraph 645 involved dispensing activities that occurred outside of Ohio, and denies the remaining allegations.

765. Kroger joins in Plaintiff's demand that the above-captioned action be tried to a jury. Inasmuch as Plaintiff's Amended Complaint indicates that a jury trial has already been requested, a jury fee is not tendered herewith. However, in the event that a jury trial is not provided based on the request of Plaintiff, Defendants will tender the appropriate fee.

KROGER'S DEFENSES

Having answered the allegations of Plaintiff's Amended Complaint, and having denied any liability whatsoever, Kroger further denies any allegations that have not been expressly admitted and sets forth below its defenses. By setting forth these defenses, Kroger does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, Kroger does not intend these defenses to be, nor shall they be construed as, an acknowledgement that any particular issue or subject matter is relevant to Plaintiff's allegations. Kroger does not admit or acknowledge that it bears the burden of proof or burden of persuasion with respect to any such defense. Upon completion of discovery, if the facts warrant, Kroger may withdraw any of these defenses as may be appropriate. Kroger reserves the right to (i) rely on any other applicable defenses set forth in any Answer or listing of defenses of any other defendant in this Action, (ii) rely on any other defenses that may become apparent during fact or expert discovery in this matter, and (iii) to amend its Answer to assert any such defenses.

First Defense

The Amended Complaint fails to state a claim against these Defendants upon which relief can be granted.

Second Defense

This Court lacks subject matter jurisdiction over all or some of the claims asserted by the Plaintiff.

Third Defense

To the extent applicable, the Court lacks subject matter jurisdiction to address any violations of the North Carolina Pharmacy Practice Act, either (1) for failure to comply with any administrative remedies under the Act, (2) because the North Carolina Pharmacy Practice Act does not give rise to a private cause of action, and/or (3) because the Court has already dismissed any claims or cause of action arising from or related to the North Carolina Pharmacy Practice Act.

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrine.

Fifth Defense

The Plaintiff lacks standing to assert all or some of its claims in this lawsuit.

Sixth Defense

Plaintiff's claims are barred by the voluntary payment doctrine.

Seventh Defense

Plaintiff's claims are barred by the doctrine of unclean hands.

Eighth Defense

Plaintiff's claims are barred by the doctrine of *in pari delicto*.

Ninth Defense

Plaintiff's claims are not ripe and/or have been mooted.

Tenth Defense

Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality.

Eleventh Defense

Plaintiff's claims are barred because Plaintiff are not the real parties in interest.

Twelfth Defense

Plaintiff's claims are subject to all defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf Plaintiff seek to recover.

Thirteenth Defense

Any injuries and/or damages sustained by Plaintiff may have been caused or contributed to by the negligence or actual conduct of Plaintiff and/or other persons, firms, corporations, or entities over whom Kroger had no control or right of control and for whom it is not responsible.

Fourteenth Defense

A specific percentage of the tortious conduct that proximately caused the injury or loss to person or property is attributable to (i) Plaintiff, (ii) other parties from whom Plaintiff seeks recovery, and (iii) persons from whom Plaintiff does not seek recovery in this action, including, but not limited to, prescribing practitioners, non-party pharmacies and pharmacists, individuals and entities involved in diversion and distribution of prescription opioids, individuals and entities involved in import, distribution, and sale of illegal opioids, individuals involved in procuring diverted prescription opioids and/or illegal drugs, delivery services, federal, state, and local

government entities, and health insurers and pharmacy benefit managers, pursuant to the doctrine of comparative fault.

Fifteenth Defense

Any recovery by Plaintiff must be reduced to account for the acts or omissions attributable to Plaintiff.

Sixteenth Defense

Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or, with reasonable certainty, will indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss from any collateral source or any other applicable law.

Seventeenth Defense

Any damages that Plaintiff may recover against Kroger must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject drugs, or damages recovered or recoverable by other actual or potential Plaintiff. Any damages that Plaintiff may recover against Kroger must be reduced to the extent they unjustly enrich Plaintiff.

Eighteenth Defense

Plaintiff has failed to comply with the requirement that it identify each patient in whose claim(s) it has a subrogation interest and on whose behalf it has incurred costs.

Nineteenth Defense

Plaintiff fails to plead that it reimbursed any prescriptions for any opioid sold by Kroger that harmed patients and should not have been written, or that Kroger's allegedly improper conduct caused any health care provider to write any ineffective or harmful opioid prescriptions, or that any specific prescription was unauthorized, medically unnecessary, ineffective, or harmful.

Twentieth Defense

Plaintiff's claims against Kroger do not arise from the same transactions or occurrences as its claims against other defendants, as required for joinder of parties.

Twenty-First Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of superseding and intervening acts and/or causation.

Twenty-Second Defense

To the extent Plaintiff has made a civil conspiracy claim against these Answering Defendants, and such claim has not been dismissed by the Court, there is no basis for joint and several liability among the Defendants, and Plaintiff's civil conspiracy should be dismissed, as it is an improper attempt to obtain such a result.

Twenty-Third Defense

Plaintiff's claims are barred, in whole or in part, because Kroger has no legal duty to protect Plaintiff from the intentional criminal acts of third persons. Such criminal acts are superseding causes that extinguish any liability.

Twenty-Fourth Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were due to illicit use or abuse of medications.

Twenty-Fifth Defense

Plaintiff's claims are barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bars Plaintiff from recovering payments it allegedly made on behalf of its residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

Twenty-Sixth Defense

Plaintiff's claims are barred, in whole or in part, to the extent that it violated the Dormant Commerce Clause of the United States Constitution.

Twenty-Seventh Defense

The Amended Complaint fails to state a claim against Kroger because Plaintiff cannot establish a right common to the general public with which Kroger unreasonably interfered.

Twenty-Eighth Defense

Kroger did not owe or breach any statutory or common law duty to Plaintiff.

Twenty-Ninth Defense

Kroger appropriately, completely, and fully performed and discharged any and all obligations and legal duties arising out of the matters alleged in the Amended Complaint.

Thirtieth Defense

Plaintiff's claims are barred, in whole or in part, because Kroger complied at all relevant times with all applicable laws, including all legal and regulatory duties.

Thirty-First Defense

Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on Kroger.

Thirty-Second Defense

To the extent applicable, Kroger is not a Wholesale Distributor as alleged in the Amended Complaint and, hence, the Amended Complaint is premised on a mistaken allegation against Kroger and should be dismissed against Kroger for that reason.

Thirty-Third Defense

Kroger raises the Learned Intermediary Defense to the extent applicable, based on the allegations against Kroger, because Kroger fills valid prescriptions written by a physician acting in the capacity of a learned intermediary.

Thirty-Fourth Defense

Any and all of the injuries or damages suffered by Plaintiff resulted solely from conduct and/or conditions for which Kroger is not responsible and for which it cannot be held liable.

Thirty-Fifth Defense

Plaintiff's claims are barred, in whole or in part, because the harm alleged was proximately caused by the negligence, gross negligence, or intentional and malicious acts of intervening third parties not under Kroger's control, including, without limitation, pre-existing medical conditions.

Thirty-Sixth Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by the misuse of the medications involved, by failure to use the medications properly, and/or by the alteration, modification, or criminal misuse of medications prescribed by third parties over whom Kroger had no control.

Thirty-Seventh Defense

Plaintiff's claims are barred, in whole or in part, because neither the users of the subject prescription medications nor their prescribers relied to their detriment upon any statement by Kroger in determining to use or prescribe the subject prescription medications.

Thirty-Eighth Defense

Plaintiff's claims against Kroger are improperly joined with Plaintiff's claims against other Defendants and must be severed.

Thirty-Ninth Defense

Plaintiff's claims against Kroger are barred because Kroger has complied with all applicable laws or regulations of the federal government and the State of North Carolina.

Fortieth Defense

Plaintiff's claims against Kroger are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.

Forty-First Defense

Plaintiff's claims are barred, in whole or in part, by Plaintiff's comparative or contributory fault including without limitation, on information and belief, its failure to:

a. Develop and implement adequate policies and procedures to license and monitor physicians and other professionals prescribing the controlled substances at issue in the Amended Complaint, and to discipline or terminate the licenses of those issuing prescriptions for other than legitimate purposes;

b. Develop and implement adequate policies and procedures to license, monitor and inspect pain management clinics prescribing the controlled substances at issue in the Amended Complaint, and to discipline or terminate the licenses of those issuing prescriptions for other than legitimate purposes;

c. Develop and implement adequate policies and procedures to license, monitor and inspect pharmacies, pharmacists and other dispensers to ensure that they filled only legitimate prescriptions for controlled substances at issue in the Amended Complaint, and to

discipline or terminate the licenses of those dispensing such prescription drugs for other than legitimate purposes;

d. Develop and mandate use of an effective controlled substance monitoring database to identify rogue pharmacies, other dispensers and doctors, and drug abusers and take appropriate action against them;

e. Develop, implement and adequately fund prescription drug abuse prevention and treatment programs;

f. Develop, implement and adequately fund programs to address homelessness within the State of North Carolina;

g. Adequately fund mental and behavioral health services throughout the State of North Carolina;

h. Adequately police the illicit diversion and consumption of prescription medications, and to enforce the North Carolina Controlled Substances Act, the North Carolina Pharmacy Practice Act and regulations promulgated thereunder.

Forty-Second Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff failed to join one or more indispensable parties.

Forty-Third Defense

To the extent applicable, Plaintiff's claims against Kroger are barred, in whole or in part, by the applicable statutes of limitations and repose.

Forty-Fourth Defense

Plaintiff's claims are barred, in whole or in part, because they violate the *Ex Post Facto* clauses of Article I of the United States Constitution and Article I, Sec. 16 of the North

Carolina Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Forty-Fifth Defense

Recovery from Kroger is barred, in whole or in part, by the free public services doctrine.

Forty-Sixth Defense

Plaintiff's claims against Kroger are barred, in whole or in part, by the economic loss and/or municipal cost recovery doctrine.

Forty- Seventh Defense

Plaintiff's claims are barred, in whole or in part, by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution as well as Article I, Section 19 of the North Carolina Constitution, because substantive due process forbids the retroactive imposition and unclear legal interpretations of the North Carolina Controlled Substances Act and its federal counterpart, including, without limitation, the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA").

Forty-Eighth Defense

Kroger's rights under the Due Process Clause of the U.S. Constitution and North Carolina State Constitution or statutes are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff's use of a contingency fee contract with private counsel.

Forty-Ninth Defense

Plaintiff's claims are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Amended Complaint.

Fiftieth Defense

Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

Fifty-First Defense

Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

Fifty-Second Defense

To the extent Plaintiff asserts claims that depend solely on violations of federal law, including any claims with respect to Kroger's compliance with statutes or regulations administered and/or enforced by the DEA, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

Fifty-Third Defense

Plaintiff's claims are barred to the extent they are based on any allegations involving failure to provide adequate warnings or information, because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

Fifty-Fourth Defense

To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish Kroger's regulatory duties, such informal guidance cannot enlarge Kroger's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

Fifty-Fifth Defense

Plaintiff's claims are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

Fifty-Sixth Defense

Kroger is not liable for any statements in the Manufacturer Defendants' branded or unbranded materials.

Fifty-Seventh Defense

Plaintiff's claims are barred, in whole or in part, because the State of North Carolina specifically licensed Kroger to distribute the controlled substances referred to in the Amended Complaint to purchasers with valid prescriptions within the relevant Counties in North Carolina.

Fifty-Eighth Defense

Plaintiff's commencement and prosecution of this action is arbitrary and capricious, and its claims are contrary to the North Carolina Controlled Substances Act, N.C. Gen. Stat. Ann. § 90-86, *et seq.*, and rules and regulations promulgated pursuant to that Act and its federal counterpart.

Fifty-Ninth Defense

Plaintiff's claims against Kroger are barred, in whole or in part, because it has suffered no damages because of the matters alleged in the Amended Complaint.

Sixtieth Defense

The Plaintiff is not entitled to the asserted damages, as it seeks as damages the costs it allegedly incurred in providing public services, to the extent there is no express statutory provision establishing such a remedy.

Sixty-First Defense

Any injuries and/or damages sustained by Plaintiff were caused, in whole or in part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff is barred or, alternatively, should be diminished according to its own fault.

Sixty-Second Defense

Any recovery by Plaintiff may be barred or limited by the principles of informed consent and assumption of the risk, whether primary, express, or implied.

Sixty-Third Defense

Kroger asserts its right to a proportionate reduction, based on the negligence or other conduct of any settling tortfeasor, responsible third party, or Plaintiff, of any damages found against Kroger.

Sixty-Fourth Defense

To the extent that Plaintiff seeks equitable relief against Kroger, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

Sixty-Fifth Defense

Plaintiff's claims for unjust enrichment are barred because Kroger has not accepted or retained any benefits under circumstances where it would be inequitable for Kroger to do so.

Sixty-Sixth Defense

Plaintiff's claims for unjust enrichment are barred because Plaintiff has no authority to bring such claims on behalf of itself or the citizens of North Carolina.

Sixty-Seventh Defense

Plaintiff's claims for unjust enrichment are barred because Plaintiff did not pay Kroger any of the amounts sought.

Sixty-Eighth Defense

Plaintiff's public nuisance claim are barred to the extent that it lacks the statutory authority to bring a public nuisance claim under North Carolina law or their own applicable county or municipal codes or regulations.

Sixty-Ninth Defense

Plaintiff's claim of public nuisance is barred or limited because no action of Kroger involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against Kroger sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of Kroger is too remote from the alleged injury as a matter of law and due process.

Seventieth Defense

To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct for causes of action not already dismissed by the Court, Plaintiff has failed to plead fraud with sufficient particularity as required by Rule 9(b) of the North Carolina Rules of Civil Procedure.

Seventy-First Defense

Plaintiff's claims are barred, in whole or in part, because Kroger did not engage in misleading, unfair, actionable misrepresentation, or deceptive conduct.

Seventy-Second Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest because of the conduct of Kroger as alleged in the Amended Complaint.

Seventy-Third Defense

Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate damages.

Seventy-Fourth Defense

Plaintiff's claims are barred, in whole or in part, because the claims are speculative, uncertain, hypothetical, and remote; and because of the impossibility of ascertaining and allocating the alleged damages.

Seventy-Fifth Defense

Plaintiff's claims are barred to the extent they relate to Kroger's alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of North Carolina.

Seventy-Sixth Defense

Plaintiff's claims are barred to the extent they rely, explicitly or implicitly, on a theory of market-share liability.

Seventy-Seventh Defense

Plaintiff's claims for injunctive relief are barred because they are punitive in nature.

Seventy-Eighth Defense

Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable North Carolina statutory and common law regarding setoffs.

Seventy-Ninth Defense

Plaintiff's claims are barred, reduced, and/or limited to the extent that Kroger is entitled to a credit or setoff for all sums Plaintiff has received in the way of any and all settlements.

Eightieth Defense

Plaintiff's Amended Complaint is barred, in whole or in part, by the doctrines of acquiescence, settlement, or release.

Eighty-First Defense

Kroger's liability, if any, will not result from their conduct but is solely the result of an obligation imposed by law and, thus, Kroger is entitled to complete indemnity, express or implied, by other parties.

Eighty-Second Defense

Plaintiff cannot obtain relief on its claims, based on actions undertaken by Kroger, of which Kroger provided notice of all material facts.

Eighty-Third Defense

Kroger asserts all applicable defenses under Federal Rules of Civil Procedure 8(c) and 12(b) and/or North Carolina Rules of Civil Procedure 8(c) and 12(b), as investigation and discovery proceed.

Eighty-Fourth Defense

Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and Article I, Section 120, Article I, Section 27 of the North Carolina Constitution. Any law, statute or other authority purporting to permit the recovery

of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Defendants the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

Pursuant to N.C. Gen. Stat. Ann. § 1D-15, the Plaintiff's claims for punitive damages must be established by clear and convincing evidence.

Plaintiff's claims for punitive damages are barred by the statute of limitations and requirements set forth in N.C. Gen. Stat. Ann. §§ 1D-15, 1-52.

Eighty-Fifth Defense

Plaintiff fails to assert claims and allege facts specific to Kroger sufficient to imply its participation in a civil conspiracy.

Eighty-Sixth Defense

To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 2 Stat. 1040, 21 U.S.C. §301.

Eighty-Seventh Defense

The North Carolina Unfair and Deceptive Trade Practices Act cannot lie against Kroger as a matter of law and have not factual basis, entitling Kroger to its attorneys' fees and costs. Kroger also affirmatively seeks recovery for attorney's fees and costs arising from having to defend against claims or defenses made in bad faith. N.C. Gen. Stat. § 75-16.1(1).

Eighty-Eighth Defense

Plaintiff has failed to state its damages with specificity as required under Rule 9(g) of the North Carolina Rules of Civil Procedure.

Eighty-Ninth Defense

Plaintiff's public nuisance claim is precluded by the North Carolina legislature's comprehensive regulation of drugs of abuse. N.C. Gen. Stat. Ann. § 90-85.6(a).

Ninetieth Defense

Plaintiff's claims are barred, in whole or in part, by collateral estoppel. *Williams v. Peabody*, 719 S.E.2d 88 (2011).

Ninety-First Defense

Plaintiff's claims are barred, in whole or in part, by res judicata. *Whitacre P'ship v. BioSignia, Inc.*, 591 S.E.2d 870 (2004).

Ninety-Second Defense

Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable North Carolina statutory and common law regarding liability caps. N.C. Gen. Stat. Ann. §§ 1D-25(b), 90-21-19.

WHEREFORE, Kroger respectfully asks that this Court:

- A. Dismiss Plaintiff's Amended Complaint, with prejudice, for the reasons set forth in Kroger's Answer;
- B. Award Kroger its costs of litigation, including reasonable attorney and other fees incurred;
- C. Grant such other and further relief, including declaratory and equitable relief, as the Court deems appropriate.

JOINDER IN JURY DEMAND

Kroger joins in Plaintiff's demand that the above-captioned action be tried to a jury. Inasmuch as Plaintiff's Amended Complaint indicates that a jury trial has already been requested, a jury fee is not tendered herewith. However, in the event that a jury trial is not provided based on the request of Plaintiff, Defendants will tender the appropriate fee.

DATED this 3rd day of December 2021.

**THE KROGER CO., KROGER LIMITED
PARTNERSHIP I AND KROGER LIMITED
PARTNERSHIP II, HARRIS TEETER, LLC
F/K/A FOOD WORLD, INC. F/K/S HARRIS
TEETER, INC. F/K/A HARRIS-TEETER
SUPER MARKETS, INC. F/K/A RACC, INC.,**

By Counsel

/s/ Ronda L. Harvey

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that true and correct copy of the foregoing **KROGER DEFENDANTS' ANSWER TO PLAINTIFF'S SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO "SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING DEFENDANTS AND JURY DEMAND"** was served via the Court's CM/ECF system to all counsel of record via electronic filing on this 3rd day of December 2021.

/s/ Ronda L. Harvey
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